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SGS INSTITUT FRESENIUS

# Test Report 4681915-02
# 07.11.2018

## Epicutaneous Test for the Assessment of a Skin-Irritation Potential

## Sponsor:
## SEDO Chemicals Neoprene GmbH
## D-15517 Fürstenwalde

## Mr. Roland Loch

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Test Report: 4681915-02 dated 07.11.2018
Sponsor: Sedo Chemicals GmbH, 15517 Fürstenwalde (Deutschland)
Test Items: 180895190

# Test Report 4681915-02

| | | | |
|---|---|---|---|
| **Test Description:** | Assessment of a skin-irritating potential in an epicutaneous test. | | |
| **Sponsor:** | **SEDO Chemicals Neoprene GmbH**<br>Tränkeweg 18a<br>**D-15517 Fürstenwalde** | | |
| **Contact:** | Mr. Roland Loch | | |
| **Date of Order:** | 05.09.2018 | | |
| **Date of Report:** | 07.11.2018 | | |
| **Order Number.:** | 4681915 | | |
| **Number of volunteers:** | Number | : | 30 volunteers |
| | | : | 18 sensitive skin<br>3 atopic diathesis |
| | Age | : | 21 – 63 Years |
| | Sex | : | male (9 volunteers)<br>femal (21 volunteers) |
| **Testarea:** | back | | |
| **Testing period:** | 08.10. – 11.10.2018 (control times: 24 & 48 hours) | | |
| **Applied Quantity:** | 1 x 1 cm | | |
| **Test Concentration:** | pure | | |
| **Labor:** | Taunusstein (Germany) | | |
| **Dermatologist:** | Frau Dr. Schorling | | |

**Test Items:**

| |
|---|
| **180895190**<br>Neopren (Typ "S", unkaschiert) |



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# Study Objective

The epicutaneous test is used for the assessment of primary skin irritation as well as localized and temporary contact allergies for test items.

# Summary

Under the coosen test conditions 16 subjects showed a clear reaction on the positive control '1 % SDS'. No subject showed a reaction on the negative control 'distilled water'. No subject showed a reaction on the test product.

The claim "**dermatologically tested**" was substantiated by dermatological supervision of the study by a dermatologist and the confirmation of skin tolerance.

**Conclusion:**
**The test product can be classified as very well tolerated by the skin.**

We hope to have served you satisfactorily with our investigations. We are at your disposal for any further requests.

Yours sincerely,

**SGS INSTITUT FRESENIUS GmbH**

i.V. Dr. Ines Sellami
(Leader Hair and Skin Care - Performance Testing Lab)

i. A. Selina Renner
(Customer Service Assistant)

**Attachments:**
- Test Method
- Results



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## ATTACHMENTS

### Test Method:

A panel of 18 persons with sensitive skin and 3 persons with atopic skin diathesis (sensitive panel), 21 female and 9 male subjects aged 21-63 years, participated in the study (see attached list of volunteers in Appendix 1).

For the epicutaneous test the undiluted test item was applied onto the clinically healthy skin on the back of volunteers and fixed with a semi-occlusive test-patch (Leukotest®, Patch area: 11mm diameter). The controls were applied occlusiv. The patch was removed 24 h later. After another 24 h, potential skin reactions were documented by a dermatologist. After additional 24 h test areas were controlled again. The occurrence of skin irritations was documented regarding intensity and temporal development.

Classification scale:

| Erythema | Score |
|---|---|
| no impression of erythema | 0 |
| Doubtful reactions | 0.5 |
| Weak, spotty erythema | 1 / 1.5 |
| Moderate erythema, sharply defined | 2 / 2.5 |
| Medium strong erythema | 3 / 3.5 |
| Strong large-surface erythema with edema | 4 / 4.5 |



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## ATTACHEMENTS

**180895190** Neopren (Typ "S", unkaschiert)

**Tab.:** Biometric data and study results

| no | Sex | Age [years] | Skin diathesis | Erythema Score | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | 1 % SDS | | Distilled water | | 180895190 | |
| | | | | 24 h | 48 h | 24 h | 48 h | 24 h | 48 h |
| 1 | f | 28 | sensitive | 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | f | 28 | atopic | 0 | 0 | 0 | 0 | 0 | 0 |
| 3 | f | 33 | sensitive | 0 | 0 | 0 | 0 | 0 | 0 |
| 4 | m | 31 | sensitive | 1 | 0 | 0 | 0 | 0 | 0 |
| 5 | m | 32 | sensitive | 1 | 1 | 0 | 0 | 0 | 0 |
| 6 | f | 42 | normal | 1 | 0,5 | 0 | 0 | 0 | 0 |
| 7 | f | 49 | sensitive | 1 | 0 | 0 | 0 | 0 | 0 |
| 8 | f | 44 | normal | 1 | 0 | 0 | 0 | 0 | 0 |
| 9 | m | 43 | normal | 3 | 2,5 | 0 | 0 | 0 | 0 |
| 10 | m | 40 | atopic | 0 | 0 | 0 | 0 | 0 | 0 |
| 11 | f | 63 | sensitive | 1 | 0,5 | 0 | 0 | 0 | 0 |
| 12 | f | 63 | normal | 0 | 0 | 0 | 0 | 0 | 0 |
| 13 | f | 56 | sensitive | 0 | 0 | 0 | 0 | 0 | 0 |
| 14 | f | 26 | sensitive | 0 | 0 | 0 | 0 | 0 | 0 |
| 15 | f | 34 | normal | 1 | 0,5 | 0 | 0 | 0 | 0 |
| 16 | f | 43 | normal | 0 | 0 | 0 | 0 | 0 | 0 |
| 17 | f | 38 | normal | 1 | 0,5 | 0 | 0 | 0 | 0 |
| 18 | f | 55 | normal | 0 | 0 | 0 | 0 | 0 | 0 |
| 19 | m | 52 | sensitive | 2 | 2 | 0 | 0 | 0 | 0 |
| 20 | f | 56 | atopic | 2 | 0 | 0 | 0 | 0 | 0 |
| 21 | f | 48 | sensitive | 3 | 2,5 | 0 | 0 | 0 | 0 |
| 22 | m | 28 | normal | 0 | 0 | 0 | 0 | 0 | 0 |
| 23 | m | 30 | normal | 2 | 2 | 0 | 0 | 0 | 0 |
| 24 | f | 32 | sensitive | 0 | 0 | 0 | 0 | 0 | 0 |
| 25 | f | 45 | normal | 2 | 2 | 0 | 0 | 0 | 0 |
| 26 | m | 26 | normal | 0 | 0 | 0 | 0 | 0 | 0 |
| 27 | m | 27 | sensitive | 1 | 0,5 | 0 | 0 | 0 | 0 |
| 28 | f | 23 | normal | 0 | 0 | 0 | 0 | 0 | 0 |
| 29 | f | 21 | normal | 3 | 0,5 | 0 | 0 | 0 | 0 |
| 30 | f | 26 | sensitive | 0 | 0 | 0 | 0 | 0 | 0 |

*end of report*



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